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10/511,007	05/20/2005	Hubert Clemens Pellikaan	470-045386	6713

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EXAMINER

HINDENLANG, ALISON L

ART UNIT	PAPER NUMBER
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4151

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,007	Applicant(s) PELLIKAAN ET AL.	
	Examiner ALISON HINDENLANG	Art Unit 4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/12/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities:

- a. The disclosure lacks a brief description of the drawings. See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

b. On page 6, lines 28-30 the specification recites “the admixture of additional solvent besides speeding up the particle growth process, additionally offers the advantage that it can be used to remove virtually all of the solvent contained in the precipitated particles” which is unclear. After consideration of the context, the examiner considers that the sentence should read –the admixture of additional antisolvent— and recommends that applicant amend to such. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 15, 17-18, 21-22, and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanna (US 6440337). With respect to claim 15, Hanna ‘337 teaches:

A process for the preparation of small particles through precipitation (“a method for forming particles of a substance”, column 1, line 55), which process employs a fluid solution comprising a solvent and solute (“a solution or suspension of the substance in a vehicle”, column 1, lines 58-59) to be precipitated and a non-gaseous antisolvent (“supercritical fluid”, column 1, line 58), said solvent being soluble in or miscible with the antisolvent (“substantially soluble in the chosen supercritical fluid”, column 3, lines 48-49) and said solute being substantially insoluble in the antisolvent, wherein the process comprises the successive steps of:

- a. feeding a stream of the fluid solution and a stream of the antisolvent into a mixing zone (“primary nozzle passages”, column 6, line 57) where both streams are thoroughly mixed to achieve a condition of super saturation (“contact between a solution/suspension passing through the inner passage and a first supercritical fluid passing through a surrounding passage” column 6, lines 60-63);
- b. feeding the resulting mixture of the fluid solution and the antisolvent into a nucleation zone (“particle formation chamber”, column 1, lines 56-57) allowing nucleation to commence;

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("disperse the solution or suspension", column 1, lines 64)

c. allowing the nuclei formed in the nucleation zone to grow ("extract the vehicle", column 1, line 65) to particles with a volume weighted average diameter of no more than 50 μm ; ("median particle diameter 3276 nm", Table 1, Example 1)

d. collecting the particles ("collecting the particles", column 5, line 55) and separating them from the antisolvent ("recovering the solution", column 5, line 57);

and wherein during or following step b., and prior to step d. additional antisolvent is admixed to the mixture of the fluid solution and the antisolvent. ("simultaneously introducing into the particle formation chamber, an impinging flow of a second supercritical fluid", column 1, lines 60-61).

6. With respect to claim 17, Hanna '337 further teaches:

The process according to claim 15, wherein the antisolvent is admixed at least 1 second after completion of step a. ("the outlets of the primary nozzle passages should be reasonably close to that of the secondary nozzle passage", column 6, lines 49-50)

7. With respect to claim 18, Hanna '337 further teaches:

wherein the ratio of the solution flow rate to antisolvent flow rate in step a. is between 5:1 and 1:10 ("the ratio of the solution/suspension flow rate to each supercritical fluid flow rate will be between 0.001 and 0.2", column 3, lines 1-3)

8. With respect to claim 21, Hanna '337 further teaches:

wherein less than 25% of the nuclei ("a degree of dispersion and extraction", column 6, line 65) formed in the process are formed in the mixing zone ("before further dispersion by the second supercritical fluid", column 6, lines 66-67)

9. With respect to claim 22, Hanna '337 further teaches:

wherein the residence time within the mixing zone is less than 15 seconds. ("the first and second supercritical fluids will usually, although not necessarily, meet at or very close to the point of particle formation, ie, the point at which they contact the solution or suspension", column 3, lines 35-38)

10. With respect to claim 25, Hanna '337 further teaches:

wherein the solution comprises between 0.0001 and 30 wt.% of the solute. ("a 0.625% w/v solution of nicotinic acid in absolute ethanol", column 13, lines 10-11, example 1)

11. With respect to claim 26, Hanna '337 further teaches:

wherein the antisolvent is a supercritical or nearcritical fluid ("a fluid substantially at or above its critical pressure (P_c) and critical temperature(T_c) simultaneously", column 3, lines 40-42).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 16, 19-20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna (US 6440337). With respect to claim 16, Hanna '337 discloses the claimed invention except for "wherein the additional antisolvent is admixed after the precipitated particles have grown to a volume weighted average diameter of at least 0.1 μm ". It would have been obvious to one having ordinary skill in the art at the time of the invention to allow for this amount of particle growth before the second addition of antisolvent where larger particle sizes are desired since Hanna '337 discloses that "a degree of dispersion and extraction can occur before further dispersion by the second supercritical fluid" (column 6, lines 65-67) and it has been held that where

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the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to allow for this amount of particle growth before the second addition of antisolvent where larger particle sizes are desired. *See In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

15. With respect to claim 19, Hanna '337 discloses the claimed invention except for "wherein the collected particles, when reaching the end of the nucleation zone or immediately prior to the admixture of additional antisolvent, contain at least 1 wt % solvent". It would have been obvious to one having ordinary skill in the art at the time of the invention to maintain fluid flow rates such that some of the solvent vehicle remained present after the initial addition of antisolvent for the purpose of controlling particle size since Hanna '337 discloses that "the size of the fluid elements formed on dispersion, will depend on the relative flow rates of the fluids" (column 6, lines 46-48) and it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to maintain fluid flow rates such that some of the solvent vehicle remained present after the initial addition of antisolvent for the purpose of controlling particle size. *See In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

16. With respect to claim 20, Hanna '337 discloses the claimed invention except for "wherein the additional antisolvent is admixed in an amount effective to reduce the solvent content of the collected particles to less than 1 wt %". It would have been obvious to one having ordinary skill in the art at the time of the invention to control the

fluid flow rates such that the amount of solvent present in the collected particles is low because this aids in particle formation control since Hanna '337 discloses that "the vehicle will represent no more than around 5% mole fraction of the supercritical fluids" (column 5, lines 23-24) which "allows improved control over particle characteristics and substantially eliminates the risk of residual vehicle in the particulate product" (column 5, lines 30-32) and it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to control the fluid flow rates such that the amount of solvent present in the collected particles is low because this aids in particle formation control. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

17. With respect to claim 23, Hanna '337 discloses the claimed invention except for "wherein the mixing energy applied in the mixing zone exceeds 1 J/kg". It would have been obvious to one having ordinary skill in the art at the time of the invention to apply significant amounts of energy to the mix zone for the purpose of providing a high degree of dispersion in order to control particle uniformity since Hanna '337 discloses that "the solution/suspension can be subjected to a very high degree of dispersion due to the high overall supercritical fluid velocity (ie, high overall kinetic energy)" (column 2, lines 33-35) which "can provide a high degree of uniformity in the particles formed" (column 2, lines 37-38) and it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to apply significant amounts of energy to the

mix zone for the purpose of providing a high degree of dispersion in order to control particle uniformity. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

18. With respect to claim 24, Hanna '337 discloses the claimed invention except for "wherein the residence time within the nucleation and growth zone is at least 3 seconds". It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the length of the growth zone and the residence time therein in order to control particle size. since Hanna '337 discloses that "the size and shape of the intermediate chamber may be used in part to determine the characteristics of the particles formed" (column 7, lines 49-51) and it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to modify the length of the growth zone and the residence time therein in order to control particle size. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

19. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna (US 6440337) as applied to claim 15 above, and further in view of Hanna (US 6576262). Hanna '337 remains as applied above. Hanna '337 does not teach:

wherein the particles obtained from step c. have a particle size distribution with a standard deviation of less than 50% of the volume weighted average particle size.

In the same field of endeavor, the production of particles via precipitation with supercritical fluids, Hanna '262 teaches a process where the product has a mean size of 14.13 μm and a standard deviation of 1.611 (column 14, example 2, table 4) for the benefit of producing uniform solute particles with high purity. It would have been

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obvious to one of ordinary skill in the art at the time of the experiment to modify the process taught by Hanna '337 using conditions taught by Hanna '262 for the benefit of producing uniform solute particles with high purity.

20. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna (US 6440337) as applied to claim 15 above, and further in view of Avontuur (US 6830714). Hanna '337 remains as applied above. Hanna '337 does not teach:

wherein at least 10 wt.% of the solute present in the stream of the fluid solution of step a. is recovered in the particles obtained in step d.

In the same field of endeavor, the production of particles via precipitation with supercritical fluids, Avontuur '714 teaches, "the proportion of nabumetone was consistent between 78.9 – 80.5 % w/w over a number of runs of the process" (example 3, column 15, lines 26-27) for the purpose of isolating and recovering the starting solute in small, fine particles. It would have been obvious to one of ordinary skill in the art at the time of the experiment to modify the process taught by Hanna '337 using conditions taught by Avontuur '714 for the purpose of isolating and recovering the starting solute in small, fine particles.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grothe (US 7332111) also describes a process for the production of particles wherein the first step, prior to nucleation and growth, is contacting the solvent/solute solution with a compressed fluid antisolvent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALISON HINDENLANG whose telephone number is (571) 270-7001. The examiner can normally be reached on Monday to Thursday 7:30 - 5 pm; Every other Friday 7:30 - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on 571-272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALH

***/Angela Ortiz/
Supervisory Patent Examiner, Art Unit 4151***